K082362

MAY - 1 2009

Section II. 510(k) SUMMARY

A. Device Name

Proprietary Name

TERUMO® Surshield® SAFETY I.V. CATHETER (51mm catheter) or similar proprietary name

Classification Name

Intravascular Catheter (880.5200)
Panel & Product Code: FOZ
Classification: Class II

Common Name

Intravascular catheter with needle protection device

B. Predicate Device

The TERUMO® Surshield® SAFETY I.V. CATHETER (51mm catheter) manufactured by Terumo Corporation is substantially equivalent to with respect to intended use, design, technology/principles of operation, materials and performance:

- K082362 TERUMO® Surshield® SAFETY I.V. CATHETER

The differences between the devices do not raise any new issues of safety or effectiveness.

C. Intended Use

The TERUMO® Surshield® SAFETY I.V. CATHETER (51mm catheter length) is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The needle shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

D. Description

The TERUMO® Surshield® Safety I.V. Catheter (51mm catheter length) are devices consisting of an over-the needle, peripheral catheter made of a slender, flexible, radio-opaque, plastic catheter with a hub that is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system. The sharp end of the inner needle is covered by the steel guard as the needle is withdrawn from catheter's hub to aid in the prevention of needle stick injuries. This is a passive safety mechanism.

E. Principle of Operation / Technology

The TERUMO® Surshield® SAFETY IV CATHETER (51mm catheter length) is operated manually.

F. Design / Materials

1. The materials are the same materials as used in the TERUMO® Surshield® SAFETY I.V. CATHETER (K082362).

G. Specifications

TABLE I-1: Device Specifications for TERUMO® Surshield® Safety I.V. Catheter (18G × 51mm and 20G × 51mm)

Product code	Catheter gauge	Color code	Catheter length	Catheter O.D*	Catheter I.D	Cannula gauge	Flow rate	Lumen volume**
SR*SFA1851A	18G	Deep Green	2"(51mm)	1.3mm	0.95mm	20G	90mL/min	36 µL
SR*SFA2051A	20G	Pink	2"(51mm)	1.1mm	0.80mm	22G	55mL/min	26 µL

*Catheter O.D. is labeled value. **Catheter only

H. Performance

The testing was conducted in order to adhere to the performance standards and design control requirements. All performance testing conducted on the TERUMO® Surshield® SAFETY IV CATHETER (51mm sizes length) manufactured by Terumo Corporation determined that the modified device was substantially equivalent to the predicate.

I. Substantial Equivalence

The TERUMO® Surshield® SAFETY I.V. CATHETER (51mm length catheter) manufactured by Terumo Corporation is substantially equivalent to with respect to intended use, design, technology/principles of operation, safety feature, manufacturing process, materials and performance:

- K082362 TERUMO® Surshield® SAFETY I.V. Catheter

The differences between the devices do not raise any new issues of safety or effectiveness.

K. Submitter Information

Date Prepared: 03/01/2009

Prepared by: Lynne Witkowski
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Terumo Corporation
C/o Ms. Lynne Witkowski
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K090973
Trade/Device Name: TERUMO®Surshield®Safety I.V. Catheter (18G x 51mm & 20G x 51mm sizes)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 3, 2009
Received: April 6, 2009

Dear Ms. Witkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: TERUMO® Surshield® Safety I.V. Catheter (18G × 51mm & 20G × 51mm sizes)

Indications For Use:

The TERUMO® Surshield® Safety I.V. Catheter (18G × 51mm and 20G × 51mm catheter sizes) is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The needle shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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